

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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FILING DATE	FIRST NAME	D APPLICANT		ATTORNEY DOCKET NO.
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F DAVED L. ROSE MERCK & CD. INC., PAT. DEFT. F. C. BOX 2000 RAMMAY, NJ 07065

SERIAL NUMBER

06/358/736

EXAMINER

SPONNOLI

ART UNIT PAPER NUMBER

123

DATE MAILED: 117 (2001)

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on	This action is made final.
A shortened statutory period for response to this action is set to expire month(s), d Failure to respond within the period for response will cause the application to become abandoned. 3	ays from the date of this letter. 5 U.S.C. 133
Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 1. Notice of References Cited by Examiner, PTO-892. 2. Notice re Pater 3. Notice of Art Cited by Applicant, PTO-1449 4. Notice of information on How to Effect Drawing Changes, PTO-1474 6.	nt Drawing, PTO-948. mal Patent Application, Form PTO-152
Part II SUMMARY OF ACTION	
1. 🔀 Claims	are pending in the application.
Of the above, claims	are withdrawn from consideration.
2. Claims	have been cancelled.
3. 💢 Claims	are allowed.
4. X Claims	are rejected.
5. Claims	are objected to.
6. Claims are s	ubject to restriction or election requirement.
7. This application has been filed with informal drawings which are acceptable for examination matter is indicated.	on purposes until such time as allowable subject
8. Allowable subject matter having been indicated, formal drawings are required in response t	o this Office action.
9. The corrected or substitute drawings have been received on T	hese drawings are acceptable;
10. The proposed drawing correction and/or the proposed additional or substitute shee has (have) been approved by the examiner. disapproved by the examiner (see exp	et(s) of drawings, filed on lanation).
11. The proposed drawing correction, filed, has been approved the Patent and Trademark Office no longer makes drawing changes. It is now applicant's corrected. Corrections <u>MUST</u> be effected in accordance with the instructions set forth on EFFECT DRAWING CHANGES", PTO-1474.	responsibility to ensure that the drawings are
12. Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy	has been received not been received
been filed in parent application, serial no; filed on;	
13. Since this application appears to be in condition for allowance except for formal matters, paccordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.	prosecution as to the merits is closed in
14. Other	

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Claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the disclosure at pages 16-17 of the specification. See MPEP 706.03 (n) and 706.03 (z). The terms "Parasitic infections", "parasites" and "bacterial infections" are not seen to be adequately supported by specific embodiments to claim a treatment and/or composition for the above conditions.

Claims 13-16, 18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Proper Markush terminology should be employed in claims 13-16. The term "optionally" renders claim 14 alternative. The terminology "a reducing agent" is functional. In claims 18 and 20, it is not stated how much of the active ingredient is present in the pharmaceutical composition.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

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patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-16 are rejected under 35 U.S.C. 103 as being unpatentable over Sciavolino '017.

The Sciavolino '017 patent teaches the reaction of a hydroxy macrolide glycoside compound with an oxidation agent to obtain the corresponding desired keto derivative and further reaction of the keto derivative with an amine or ammonium salt to obtain the corresponding amine derivative (see column 3-6). The only novelty seen herein is in the use of another macrolide glycoside starting material. To employ the applicant's starting material in the Sciavolino process is deemed obvious to a person having ordinary skill in the art.

Claims 14-17 are rejected under 35 U.S.C. 103 as being unpatentable over Sciavolino '017 in combination with each of the Ross or Daniels et al patents. The Sciavolino patent has been fully explained supra. Each of the Ross and Daniels et al. patents shows the well known acylation of amine

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substitution glycosides and the reductive alkylation of the acylated amine derivative to the corresponding amino alkyl glycoside compound. The combination of Sciavolino's process with the process taught by Ross and Daniels et al into a single unitary process and the adaptation of the said process to the instant starting materials is deemed to be obvious to a person of ordinary skill in the art having the above disclosures before him.

JRBrown: ebw

A/C 703

557-2575

2/19/83

JOHNNIE R. BROWN PRIMARY EXAMINER ART UNIT 123